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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,271

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EXAMINER

GANGLE, BRIAN J

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/772,271	Applicant(s) ASAHARA ET AL.	
	Examiner Brian J. Gangle	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/30/06;12/22/04</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV, SEQ ID NO:2 in the response filed 9/7/2006 is acknowledged. The traversal is on the ground(s) that examination of all claims would not pose an undue burden nor constitute a non-coextensive search. This is not found persuasive for the following reasons.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I, III, and V are classified separately necessitating different searches of issued U.S. Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive in scope, because, for example, searching for bacteria used to produce polysaccharides would be quite different from those with reduced polysaccharide production. Additionally, it is submitted that the inventions have acquired a separate status in the art. Regarding the examination of multiple SEQ ID NOs, it is current office policy to restrict examination to only one sequence per application. Clearly different searches and issues are involved in the examination of each Group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9 are pending. Claims 1-6 and 9 are withdrawn as being drawn to nonelected inventions. Claims 7-8 are currently under examination.

Information Disclosure Statement

The information disclosure statements filed 4/30/2004 and 12/22/2004 have been considered. Initialed copies are enclosed.

Claim Objections

Claims 7-8 are objected to because of the following informalities: the claims are dependent upon a nonelected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is drawn to a product of nature. Products of nature are not patentable because they do not reflect the “hand of man” in the production of the product or manufacturing process. As disclosed in the specification in paragraph 0024, “...the DNA of the present invention can be isolated and obtained from a chromosomal DNA of a *Methylophilus* bacterium, for example, *Methylophilus methylotrophus*. A wild-type strain of *Methylophilus methylotrophus*, the AS1 strain (NCIMB No. 10515) is available from the National Collections of Industrial and Marine Bacteria.” Further, all bacteria are capable of reducing polysaccharide production in response to environmental stimuli. Therefore, claims 7-8 read on naturally occurring *Methylophilus methylotrophus*.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rendered vague and indefinite by the phrase “A methanol-utilizing bacterium having an ability to reduce production of a polysaccharide, wherein a gene on said bacterium's chromosome has the same nucleotide sequence as the DNA of claim 1, or which has homology to the DNA of claim 1 to such an extent that homologous recombination results in disruption of said DNA, thereby suppressing expression of the gene.” It appears, in view of the instant specification, that the embodiment being claimed would require the gene encoding SEQ ID NO:2 (*gtfA*) to be disrupted in order to reduce polysaccharide production. However, according to the

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claim, the bacterium should have *gtfA*, which would therefore not be disrupted, and would not result in reduced polysaccharide production. In the case where the DNA has homology to *gtfA*, homology is generally used to describe similarity between genes. Therefore, recombination with a homologous gene would not necessarily result in disruption of *gtfA*. Further, homologous recombination would not result in disruption of the actual DNA, it would only result in disruption of the sequence of the gene, but not of the actual strand of DNA. Additionally, the claim requires the bacterium to have the ability to reducing polysaccharide production; it does not require the bacterium to actually have reduced polysaccharide production. If the genes that allow polysaccharide production in a specific bacterium were disrupted, that bacterium would be unable to produce a given polysaccharide, and would therefore be incapable of reducing production, as one cannot decrease production below zero. Moreover, bacteria are naturally capable of modulating biosynthesis of compounds such as polysaccharides, and gene disruption is not required to make them capable of this modulation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by NCIMB Culture Collection (NCIMB Culture Collection Online Catalog, accessed 9/21/2006, <http://www.ncimb.co.uk/results.php?parent+culture>).

The instant claims are drawn to a methanol-utilizing bacterium having an ability to reduce production of a polysaccharide, wherein a gene on said bacterium's chromosome has the same nucleotide sequence as an isolated and purified DNA encoding a protein selected from the group consisting of: (A) a protein which has the amino acid sequence of SEQ ID NO: 2; (B) a variant of a protein which has the amino acid sequence of SEQ ID NO: 2 comprising substitution, deletion, insertion or addition of one or several amino acid residues and has an

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activity for producing a polysaccharide, or which has homology to an isolated and purified DNA encoding a protein selected from the group consisting of: (A) a protein which has the amino acid sequence of SEQ ID NO: 2; (B) a variant of a protein which has the amino acid sequence of SEQ ID NO: 2 comprising substitution, deletion, insertion or addition of one or several amino acid residues and has an activity for producing a polysaccharide to such an extent that homologous recombination results in disruption of said DNA, thereby suppressing expression of the gene (claim 7); wherein the bacterium is a *Methylophilus* bacterium.

NCIMB discloses the wild-type *Methylophilus methylotrophus* AS1 strain (NCIMB No. 10515) which was deposited in 1970. As disclosed in the specification in paragraph 0024, "the DNA of the present invention can be isolated and obtained from a chromosomal DNA of a *Methylophilus* bacterium, for example, *Methylophilus methylotrophus*. A wild-type strain of *Methylophilus methylotrophus*, the AS1 strain (NCIMB No. 10515) is available from the National Collections of Industrial and Marine Bacteria." Therefore, the bacterium available in 1970 from NCIMB meets the limitations of the instantly claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Mark Navarro can be reached on (571) 272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle

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ROBERT A. ZEMAN
PRIMARY EXAMINER